DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20, 2014

Vascular Flow Technologies Ltd.
Edwin Lindsay
VP of QA/RA
Prospect Business Centre, Gemini Cresent
Dundee DD2 1TY
United Kingdom

Re: K142062
Trade/Device Name: Spiral Flow Peripheral Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: October 28, 2014
Received: October 29, 2014

Dear Edwin Lindsay,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142062

Device Name
Spiral Flow™ Peripheral Vascular Graft

Indications for Use *(Describe)*
The Spiral Flow Peripheral Vascular Grafts are indicated for use as vascular prostheses.

The device is intended for use in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Vascular Flow Technologies Ltd.
Special 510(k): Device Modification

For the Spiral Flow™ Peripheral Vascular Graft

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Vascular Flow Technologies Limited

Submitter's Address:

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DD2 1TY
UK

Tel: +44 (0) 1382 598 532

Establishment Registration Number:

3007676031

Contact Person:

Edwin Lindsay
VP of QA/RA
Vascular Flow Technologies Limited

Telephone +44 (0) 7917134922

Date Prepared:

25th July 2014

Vascular Flow Technologies Ltd.
Special 510(k): Device Modification

For the Spiral Flow™ Peripheral Vascular Graft

510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
870.3450	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	Class 2	DSY	Cardiovascular

Device Trade Name:

Spiral Flow™ Peripheral Vascular Graft

Device Common Name:

Spiral Flow™ Peripheral Vascular Graft

Intended Use:

The Spiral Flow Peripheral Vascular Grafts are indicated for use as vascular prostheses.

The device is intended for use in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Predicate Device:

The modified device is substantially equivalent to the previously cleared Spiral Flow Peripheral Vascular Grafts, 510(k) number K083169

Device Description:

Vascular Flow Technologies' (VFT) Spiral Flow™ Peripheral Vascular Graft is to be used in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee; it has a specially designed section to induce spiral laminar flow.

The unique design feature translates Spiral Laminar Flow (SLF™) technology to the graft lumen profile. SLF™ technology is designed to propagate spiral flow though the graft and into the distal circulation.

The starting material for the VFT Spiral Flow™ Peripheral Vascular Graft is a straight tubular vascular graft made from expanded polytetrafluoroethylene (ePTFE).

The graft includes a helical overlay of polytetrafluoroethylene (PTFE) beading over most of the grafts length. This is heat set onto the external surface of the ePTFE tube. The function of the beading is to provide reinforcement for the tube.

Vascular Flow Technologies Ltd.
Special 510(k): Device Modification

For the Spiral Flow™ Peripheral Vascular Graft

510(k) Summary

The unique SLF™ spiral flow inducer is injection molded onto the outer surface of the straight graft. The inducer and indicator are made from ChronoFlex® C-80A; a Biodurable Medical Grade polyurethane

Comparison to Predicate Device

In comparison to the predicate device, the subject device has a new base ePTFE graft material. This modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Summary of non-clinical tests:

The following outlines the testing performed, as a result of the risk analysis, to demonstrate substantial equivelance to the predicate device:

- Biocompatibility Review
- Product Testing - Characterisation Study
- Product Testing – Flow Testing Study
- Sterilisation Validation

Conclusion:

The above test results confirmed the modified device met or exceeded the same specifications as that of the predicate device and is therefore substantially equivalent with respect to safety and efficacy to the predicate device